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Flow control devices for connection to a medical gas supply system

Dispositifs de contrôle du débit pour raccordement à un système d'alimentation en gaz médicaux

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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This document was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 6, *Medical gas supply systems*.

This third edition cancels and replaces the second edition (ISO 15002:2008), which has been technically revised. It also incorporates the Amendment ISO 15002:2008/Amd.1:2018.

The main changes are as follows:

— title changed as the requirements for *flow control devices* are the same regardless of the gas supply and they control the flow, they do not measure the flow;

— layout changed from requirements for each type of *flow control device* to the common requirements as they are the same for each *flow control device*;

— test methods have been rationalised and put into a new Annex C;

— hazard identification list added as a new Annex D;

— the maximum flow that can be achieved when the flow control is opened fully has been included as a marking requirement on the device so that the user will know what could be delivered to the patient. A rationale has also been added to cover this marking requirement;

— a new requirement has been added for stability of setting;

— the environmental conditions have been aligned with IEC 60601-1-12, emergency equipment, as *flow control devices* are used in such environments; and

— the requirement for accuracy has been rationalised for clarity.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html

Introduction

Flow control devices are used to administer a prescribed flow of gas to a patient interface device (e.g. nasal cannula, facemask) from a pressure gas source, such as a medical gas supply system. These devices need to deliver accurate flows under varying conditions of temperature and inlet pressures. Therefore, it is important that the performance characteristics be specified and tested in a defined manner.

Annex A provides additional insight into the reasoning that led to the requirements and recommendations that have been incorporated in this document. It is considered that knowledge of the reasons for the requirements will not only facilitate the proper application of this document but will expedite any subsequent revisions.

Flow control devices for connection to a medical gas supply system

1 Scope

1.1 This document specifies requirements for *flow control devices* that can be connected by the user either directly, by means of a probe or a *gas-specific* connector, or indirectly by means of a low-pressure hose assembly conforming with ISO 5359 to:

a) a terminal unit conforming with ISO 9170-1 of a medical gas pipeline system conforming with ISO 7396-1:2016;

b) the pressure outlet of a regulator conforming with ISO 10524-1:2018; or

c) to the pressure outlet of a valve integrated pressure regulator (VIPR) conforming with ISO 10524-3 (see 5.2 gas inlets).

1.2 This document applies to the following types of *flow control devices* (FCDs):

a) *flowmeters*;

b) *flowgauge FCDs*; and

c) *fixed orifice FCDs*.

NOTE *Flow control devices* that are classed as medical electrical equipment can be subject to additional requirements of IEC 60601-1.

1.3 This document applies to *flow control devices* for the following gases:

— oxygen;

— oxygen 93 %;

— nitrous oxide;

— medical air;

— carbon dioxide;

— oxygen/nitrous oxide mixture 50/50 (% volume fraction);

— oxygen-enriched air;

— helium;

— xenon; and

— specified mixtures of the gases listed above.

NOTE *Flow control devices* can be available for other gases.

1.4 This document does not apply to *flow control devices* that are:

a) for use with gases for driving surgical tools;

b) an integral part of a regulator (see ISO 10524-1:2018); or

c) an integral part of a valve with integrated pressure regulator (VIPR) (see ISO 10524-3).

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 32, *Gas cylinders for medical use — Marking for identification of content*

ISO 5359, *Anaesthetic and respiratory equipment — Low-pressure hose assemblies for use with medical gases*

ISO 7396-1:2016, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum*

ISO 9170-1:2017, *Terminal units for medical gas pipeline systems — Part 1: Terminal units for use with compressed medical gases and vacuum*

ISO 10524-1:2018, *Pressure regulators for use with medical gases — Part 1: Pressure regulators and pressure regulators with flow-metering devices*

ISO 10524-3, *Pressure regulators for use with medical gases — Part 3: Pressure regulators integrated with cylinder valves (VIPRs)*

ISO 15001, *Anaesthetic and respiratory equipment — Compatibility with oxygen*

ISO 17256[1)], *Anaesthetic and respiratory equipment — Respiratory therapy tubing and connectors*

ISO 18562-1, *Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process*

ISO 20417, *Medical devices — Information to be supplied by the manufacturer*

CGA V5, *Diameter Index Safety System (Non-Interchangeable Low Pressure Connections for Medical Gas Applications)*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

NOTE The terms defined in Clause 3 are delineated throughout this document in *italic font*.

3.1
flow control device
FCD
device that indicates the selected flow of a specific gas

Note 1 to entry: Typical examples of *flow control devices* are given in Annex B, Figure B.1.

1) Under preparation. Stage at the time of publication: ISO/DIS 17256:2023.

3.2
flowgauge FCD
flow control device that measures gas pressure and that is calibrated in units of flow

Note 1 to entry: *Flowgauge FCDs* indicate flow by measuring the pressure upstream of a fixed orifice.

3.3
flowmeter
flow control device that indicates the actual flow of gas to the patient e.g. by means of a bobbin/float within a graduated tube, or a deflected paddle

3.4
fixed orifice FCD
flow control device with a flow selector, for selecting the flow and indicating the flow selected

3.5
gas specific
having characteristics which prevent connections between different gas services or vacuum service

[SOURCE: ISO 9170-1:2017, 3.2]

3.6
rated inlet pressure P_1
upstream pressure (or pressure range) for which the *flow control device* is designed to operate

3.7
securely attached
not detachable without the use of a tool

4 General requirements

NOTE Unless otherwise specified, pressures in this document are expressed as gauge pressures (i.e. atmospheric pressure is defined as zero).

4.1 Risk management

This document specifies requirements that are generally applicable to hazards associated with *flow control devices*. Manufacturers shall apply an established risk management process to the design of *flow control devices* (e.g. ISO 14971). The risk management process should include at least the following elements:

— risk analysis;

— risk evaluation;

— risk control; and

— production and post-production information.

NOTE See Annex D for a list of hazards that can be used as guidance in the risk management process.

Check conformance by inspection of the risk management file.

4.2 Usability

Manufacturers shall apply a usability engineering process to assess and mitigate any hazards caused by usability problems associated with correct use (i.e. normal use) and use errors (e.g. IEC 60601-1-6 and IEC 62366-1).

Check conformance by inspection of the usability engineering file.

4.3 Materials

4.3.1 Materials shall be resistant to corrosion and designed to withstand the environmental conditions specified in 4.5.

Check conformance by inspection of the technical file.

4.3.2 Materials shall be compatible with the gases with which they can come into contact.

NOTE ISO 11114-1 and ISO 11114-2 can offer helpful guidance on material compatibility with gases.

Check conformance by inspection of the technical file.

4.3.3 Materials in the breathing gas pathway shall be evaluated for biocompatibility according to ISO 18562-1.

NOTE ISO 18562-1 also refers to other parts of the 18562 series for biocompatibility evaluation of particulates, volatile organic compounds and leachables.

Check conformance by inspection of the technical file.

4.3.4 Materials shall be resistant to deterioration by cleaning and disinfection or sterilization methods recommended by the manufacturer [see 7.3 h)].

Check conformance by inspection of the technical file.

4.3.5 The selection of materials shall include a systematic review of their carcinogenic, mutagenic or toxic to reproduction ('CMR') or endocrine-disrupting properties.

For those materials present in excess of 0,1 % (w/w) in any parts, a safer alternative should be used.

If no suitable alternative exists, the risk for patient or user shall be assessed taking into account the intended use and latest relevant scientific committee guidelines.

Check conformance by inspection of the technical file and the risk management file.

4.4 Oxygen compatibility

NOTE There is rationale for this subclause in A.2.

Components and lubricants used during the manufacture of *flow control devices* that come into contact with medical gases during normal use shall meet the compatibility requirements of ISO 15001.

Check conformance by inspection of the technical file.

4.5 Environmental conditions

NOTE There is rationale for this subclause in A.3.

4.5.1 Transport and storage environmental conditions

4.5.1.1 Unless different environmental conditions for transport and storage are stated by the manufacturer in their instructions for use [see 7.3 i)] *flow control devices* shall comply with the performance requirements specified in Clause 5 after being exposed, whilst packed for transport and storage, to the following environmental conditions:

a) −40 °C to +5 °C without relative humidity control;

b) >5 °C to 35 °C at a relative humidity up to 90 %, non-condensing; and

c) >35 °C to 70 °C at a water vapour pressure up to 50 hPa.

NOTE Performance requirements include: mechanical strength (5.4); leakage (5.5); accuracy (5.7) and stability of indicated flow (5.8)

Check conformance by the tests given in Annex C.

4.5.1.2 If manufacturers state a different range of environmental transport and storage conditions in their instructions for use they shall:

a) justify these transport and storage environmental conditions in their risk management file;

b) mark these transport and storage environmental conditions on the packaging; and

c) comply with the performance requirements specified in Clause 5 after being exposed, whilst packed for transport and storage, at these environmental conditions.

NOTE Performance requirements include: mechanical strength (5.4), leakage (5.5), accuracy (5.7) and stability of indicated flow (5.8)

Check conformance by:

— inspection of the risk management file;

— visual inspection of the packaging; and

— by performing the tests given in Annex C.

4.5.2 Operating environmental conditions

4.5.2.1 *Flow control devices* shall comply with the performance requirements specified in Clause 5 when operated under normal environmental conditions [i.e. a temperature of (23 ± 3) °C and an atmospheric pressure of 101,3 kPa].

NOTE Performance requirements include: mechanical strength (5.4), leakage (5.5), accuracy (5.7), stability of indicated flow (5.8) and continuous increase in flow (5.9).

Check conformance by the tests given in Annex C.

4.5.2.2 Manufacturers shall state, in their instructions for use, [see 7.3 e)], any adverse effects on the performance of their *flow control device* when subjected to the following operating environmental conditions:

a) a temperature range of 0 °C to 40 °C; and

b) an atmospheric pressure range of 620 hPa to 1 060 hPa.

Check conformance by inspection of the instructions for use.

5 Design requirements

5.1 General

Flow control devices shall be fitted with a means to prevent particles larger than 100 µm from entering the gas pathway.

Check conformance by inspection of the technical file.

5.2 Gas inlets

Gas inlets shall be *securely attached* to the *flow control device* and be either:

a) a probe complying with ISO 9170-1:2017 [e.g. see Figure B.2 a)];

NOTE ISO 9170-1:2017 does not specify the design or the dimensions of *probes*.

b) the nut and nipple of a *gas-specific* screw-threaded connector in accordance with a recognized system [e.g. diameter-indexed safety system (DISS), non-interchangeable screw-threaded (NIST) or sleeve indexed system (SIS), e.g. see Figure B.2 b)]; or

c) a *gas specific* low-pressure flexible hose assembly complying with ISO 5359 [e.g. see Figures B.2 c) and B.2 d)].

Check conformance by inspection of the technical file.

5.3 Outlet connectors

Outlet connectors shall be one of the following:

a) a *securely attached* nipple complying with ISO 17256; or

b) a *gas-specific* threaded male DISS connector complying with CGA V5.

NOTE 1 CGA V5 is referenced as ISO 17256 specifies threaded DISS connectors for oxygen and air only.

NOTE 2 A user-detachable adaptor can be used to convert the threaded outlet to a nipple as specified in ISO 17256.

Check conformance by inspection of the technical file.

5.4 Mechanical strength

NOTE There is rationale for this subclause in A.4.

Flow control devices shall withstand an inlet pressure of ≥1 200 kPa for ≥5 min without adversely affecting performance when tested under normal operating environmental conditions.

Check conformance by the test given in C.6.

5.5 Leakage

NOTE There is rationale for this subclause in A.5.

5.5.1 The internal leakage shall not exceed 0,3 ml/min at the *rated inlet pressure* P_1, specified by the manufacturer [see 7.3 b)] when the flow control is closed with a torque 0,4 Nm or the flow selector for multiple fixed orifices is set to zero.

Check conformance by the test method given in C.7.

5.5.2 The external leakage (to atmosphere) shall not exceed 0,5 ml/min at the *rated inlet pressure* P_1 when the outlet is plugged, and the flow control is opened fully or the flow selector for multiple fixed orifices set to the maximum setting.

Check conformance by the test method given in C.7.